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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|-------------------------|------------------|
| 10/019,482                       | 06/18/2002  | Gil Prive            | 2274/47985              | 5611             |
| 7590 04/21/2004                  |             |                      | EXAM                    | INER             |
| Joseph D Evans                   |             |                      | AUDET, MAURY A          |                  |
| Crowell & Moring<br>PO Box 14300 |             |                      | ART UNIT                | PAPER NUMBER     |
| Intellectual Property Group      |             |                      | 1654                    |                  |
| Washington, DC 20044-4300        |             |                      | DATE MAILED: 04/21/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.                   | Applicant(s)                |  |  |  |  |
|---|-----------------------------------|-----------------------------|--|--|--|--|
|   | 10/019,482                        | PRIVE, GIL                  |  |  |  |  |
| Office Action Summary   | Examiner                          | Art Unit                    |  |  |  |  |
|   | Maury Audet                       | 1654                        |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                                   |                             |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                   |                             |  |  |  |  |
| Status  |                                   |                             |  |  |  |  |
| 1) Responsive to communication(s) filed on 18 Ju  | <u>ıne 2002</u> .                 |                             |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ This action is non-final.   |                                   |                             |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is   |                                   |                             |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |                                   |                             |  |  |  |  |
| Disposition of Claims   |                                   |                             |  |  |  |  |
| 4) Claim(s) 1-12 is/are pending in the application.   |                                   |                             |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                                   |                             |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                                   |                             |  |  |  |  |
| 6) Claim(s) is/are rejected.  |                                   |                             |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                                   |                             |  |  |  |  |
| 8) Claim(s) <u>1-12</u> are subject to restriction and/or election requirement.   |                                   |                             |  |  |  |  |
| Application Papers  |                                   |                             |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |                                   |                             |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |                                   |                             |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                                   |                             |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |                                   |                             |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |                                   |                             |  |  |  |  |
| Priority under 35 U.S.C. § 119  |                                   |                             |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:  |                                   |                             |  |  |  |  |
| a) ☐ All b) ☐ Some c) ☐ None of.  1. ☐ Certified copies of the priority documents have been received.   |                                   |                             |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                                   |                             |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |                                   |                             |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |                                   |                             |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |                                   |                             |  |  |  |  |
|   |                                   |                             |  |  |  |  |
| A44b  |                                   |                             |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |                                   |                             |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Da               | ite                         |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 5) Notice of Informal P 6) Other: | atent Application (PTO-152) |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142 applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I.-? Claims 1-12, drawn to an amphipathic peptide conjugate comprising ANY peptide with a hydrophilic and hydrophobic face, classified in class 530, subclass 300+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-? are drawn to conjugates that are related in that they contain a peptide compound. However, because each invention (conjugate) is of an innumerably different chemical and/or peptide and/or pharmaceutical substitutions, each invention differs in structure (chemically, physically, or pharmacologically) and in function. Therefore, a separate and distinct search is required for each invention and each invention and compound is patentably distinct one from the other. [Note: Although the invention is claimed broadly as encompassing an innumerable number of peptides as useable in the conjugates, only one peptide was listed in the sequence listing. This restriction requirement is being sent because it is not known if there are any other distinctly described and searchable peptides described in the specification capable of use in the conjugate, to which Applicant may in fact elect as the preferred embodiment.

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Additionally, as indicated in Applicant's continuation application Search Report

(PCT/CA00/00773) under "Re Item III Non-establishment of opinion with regard to novelty

...": Claims 1-5 and 7-12 are not characterized by any searchable chemical or physical parameter, which makes a complete search impossible. The search was therefor based on claim 6 and on the real examples present in the text."]

The several inventions (Groups I-?) above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

## Requirement for Conjugate or Peptide Compound/Sequence Election

The inventions (I-?) do not contain a distinguishable core structure that runs through the respective conjugates claimed; therefore, an individual conjugate (with all variables of the structure defined) or a specific peptide structure and/or sequence search is required. As part of the electing one of Groups I.-? as the elected invention, Applicant is required to elect a specific

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conjugate (with all variables of the structure defined) or a specific peptide structure and/or sequence, to which the elected invention will be examined on the merits as drawn to (i.e. Claim 6's peptide sequence; since it is the only distinctly claimed peptide compound and only peptide listed in the Sequence Listing). This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM -5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, April 19, 2004

CHRISTOPHER R. TATE PRIMARY EXAMINER